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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,115	11/25/2003	Steven D. Girouard	279.597US1	4851

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EXAMINER
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BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/722,115

Applicant(s)

GIROUARD ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 70-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 70-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/04, 12/04, 6/05, 1/06, 7/06</u>                             | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Information Disclosure Statement*

1. The information disclosure statements filed 7/6/04, 12/20/04, 6/15/05, 1/23/06 and 7/12/06 have been considered and made of record.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4, 7-12, 70-73 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al.(US 6,114,164) in view of Kofidis et al.(Journal of Thoracic and Cardio. Surg.) and Farb et al.(US 6,048,722).

The reference of Dennis et al. discloses an apparatus for emulating an in vivo environment that includes a culture module (38) to host cells and culturing medium, an electrical stimulator (14) coupled to the culturing module (38), a stress simulator (16, 18, 26, 30, 40) coupled to the culturing module and a controller (20) coupled to the electrical stimulator (14) and stress simulator (16, 18, 26, 30, 40) (See Figure 1).

Claim 1 differs by reciting that the device includes a biological treatment administration module coupled to the culture module and controller.

The reference of Kofidis et al. discloses that it is known in the art to not only electrically stimulate cardiac cells in vitro but to also chemically stimulate the cells in vitro (See page 65, column 1, first paragraph).

The reference of Farb et al. discloses that biological treatment administration modules (14) are known in the art for automating the introduction of various chemical stimuli with respect to a biological material (32). The module (14) is coupled to a cell holding chamber (12) and controller (10).

In view of these teachings, it would of have been obvious to one of ordinary skill in the art to modify the device of the primary reference to include a biological treatment administration

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module for the known and expected result of allowing any cells cultured in the device of the primary reference to be additionally chemically stimulated as suggested by the reference of Kofidis et al. while allowing the automation of all the stimulation structures and detection devices.

With respect to claim 2, the reference of Dennis et al. discloses electrodes (22) in the culture chamber.

With respect to claims 3, 4 and 70, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to modify the electrical stimulation system to provide any of the known electrical stimulations that muscles cells are exposed to in vivo.

With respect to claim 7, the device of Dennis et al. includes a variable speed motor (16) and mechanical linkage (40, 30).

With respect to claims 8 and 75, the reference of Farb et al. discloses one or more chemical dispensers (18).

With respect to claim 9, the reference of Dennis et al. discloses a fluid perfusion system that would function as a mixer (See column 5, lines 35-38).

With respect to claims 10-12, 72 and 73, the reference of Dennis et al. discloses a user interface (52) that includes input device, memory and a display which allow manipulation of the conditions within the system.

With respect to claim 71, the mechanical stimulation device is structurally capable of providing in vivo stresses.

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6. Claims 5, 6, 13, 14 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al.(US 6,114,164) in view of Kofidis et al.(Journal of Thoracic and Cardio. Surg.) and Farb et al.(US 6,048,722) taken further in view of Terracio et al.(In Vitro Cell. and Develop. Bio.).

The combination of the references of Dennis et al., Kofidis et al. and Farb et al. has been discussed above.

Claims 5, 6 and 74 differ by specifying the culture substrate and mechanical linkage.

The reference of Terracio et al. discloses that it is conventional in the art to culture cardiac cells on a deformable silicone substrate when exposing the cells to mechanical stimulation (See page 53, second column) using the mechanical linkage disclosed in Figure 1.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ a silicone substrate and related mechanical linkage in the system of the modified primary reference for the known and expected result of employing an art recognized means for exposing cardiac cells to mechanical stimulation.

With respect to claims 13 and 14, the reference of Terracio et al. also discloses that microscopic observation of the cells is conventional in the art (See page 53, second column) and would have been within the purview of one having ordinary skill so as to observe the cultured cells.


### ***Conclusion***

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB